

**Attachment 4****MAY 14 2004****510(k) Summary Of Safety and Effectiveness****I. General Information**

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 CFR § 807.92

**Establishment:**

- Address: BD Diagnostics, Preanalytical Systems  
1 Becton Drive  
Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Jing Zhang  
Regulatory Affairs Manager  
Telephone no.: 201-847-4717  
Fax No. 201-847-4858
- Date of Summary: 4/23/04

**Device:**

- Trade Name: BD Vacutainer® Trace Element Serum Plus Tube  
BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube
- Classification Name: Evacuated Blood Collection Tube
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

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# **CONFIDENTIAL**

## **II Effectiveness Information Supporting Substantial Equivalence**

- Device Description

The device description of the BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube are as follows:

- Plastic tube (13x100, 6ml)
- Tube closure: Royal blue Hemogard™ closure
- Additive: Silica Clot Activator or K<sub>2</sub>EDTA

- Intended Use

The BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube are plastic evacuated blood collection tubes that provide a means of collecting, transporting, and processing blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube is used for trace element testing (e.g., Arsenic, Cadmium, Calcium, Chromium, Copper, Iron, Lead, Magnesium, Manganese, Mercury, Selenium, and Zinc).

- Synopsis of Performance Study Results

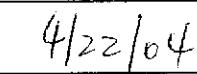
Extensive mechanical and functional testing was performed to demonstrate the devices' safety and effectiveness.

## **III. Predicate Device Summary Table**

Based on comparison of the device features, materials, intended use and performance, the BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube are shown to be substantially equivalent to the commercially available predicate devices indicated in the table below.

| Manufacturer                  | Predicate Device   | 510(k) Number |
|-------------------------------|--|---------------|
| Becton, Dickinson and Company | BD Vacutainer® Trace Element Serum Glass Tube                | Preamendment  |
|                               | BD Vacutainer® Trace Element Na <sub>2</sub> EDTA Glass Tube |               |

  
Jing Zhang  
Regulatory Affairs Manager  
BD Diagnostics, Preanalytical Systems  
Becton, Dickinson and Company

  
Date

  
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAY 14 2004

Ms. Jing Zhang  
Regulatory Affairs Manager  
Becton Dickinson & Co.  
BD Diagnostics, PreAnalytical System  
1 Becton Drive  
Franklin Lakes, NJ 07417

Re: k041071

Trade/Device Name: The BD Vacutainer®Trace Element Serum Plus Tube and BD  
Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood specimen collection device

Regulatory Class: Class II

Product Code: JKA

Dated: April 23, 2004

Received: April 26, 2004

Dear Ms. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

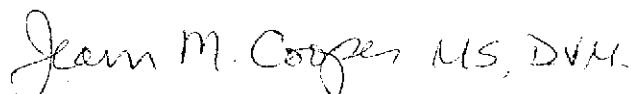
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Jean M. Cooper, MS, D.V.M.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K040171

DEVICE NAME: The BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube

### INDICATIONS FOR USE:

The BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube are plastic evacuated blood collection tubes that provide a means of collecting, transporting, and processing blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K<sub>2</sub>EDTA Plus Tube is used for trace element testing (e.g., Arsenic, Cadmium, Calcium, Chromium, Copper, Iron, Lead, Magnesium, Manganese, Mercury, Selenium, and Zinc.).

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson  
Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K040171

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